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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,664	10/29/2003	Rosalinda C. Sta-Maria	Sta-Maria-1	6832

7590 07/13/2006
Mr. Walter J. Tencza Jr.
Suite 3
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EXAMINER

LOPEZ, AMADEUS SEBASTIAN

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/696,664	Applicant(s) STA-MARIA, ROSALINDA C.	
	Examiner Amadeus S. Lopez	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 19, 20 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 19, 20 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 8, filed 4/19/2006, with respect to claims 6, 7, 19, and 20 have been fully considered and are persuasive. The rejection of claims 6, 7, 19, and 20 under 35 U.S.C. 102 based on Winthrop has been withdrawn.
2. Applicant's arguments filed 4/19/2006 have been fully considered but they are not persuasive. The arguments regarding claim 6 on page 9 in which the applicant states that the apparatus taught by Wilkie et al does not attach a nose piece to an area above the upper lip and below the nose, but rather have a different attachment mechanism is not persuasive because the flap 12 of Wilkie et al. (Fig. 6) doesn't touch a nose of the individual but touches skin between the nose and an upper lip of the individual as stated in claim 6. Therefore since claims 7, 30, 31, and 32 are dependent on claim 6, they remain rejected.
3. Applicant's arguments filed 4/19/2006 have been fully considered but they are not persuasive. The arguments regarding claim 19 on pages 10 and 11 in which the applicant states that the apparatus taught by Wilkie et al. and Landis disclose various devices and tubes which extend across the individual's face and beyond the region between the individual's eyes are not persuasive because the applicant never defines exactly what extending "substantially" beyond a region entails. Therefore using a reasonable broad interpretation of the claim, the examiner has concluded that the straps and tubes disclosed by Landis and Wilkie do not extend substantially beyond a region which lies vertically between the top of the individual's forehead and the individual's

upper lip and the region lying horizontally between a left eye and a right eye of the individual as observed in Fig. 6 of Wilkie et al. and Fig. 1 of Landis. Further the claim states that the apparatus "can" be attached to the individual's head so that the apparatus does not extend substantially beyond a region. Inherently the devices of Landis and Wilkie et al. may be placed on the head of a user without the strapping so that the apparatus does not extend substantially beyond the specified region.

4. Applicant's arguments filed 4/19/2006 have been fully considered but they are not persuasive. The arguments regarding claims 33-34 on pages 11-13 in which the applicant states that the apparatus of Wilkie et al and Landis disclose various devices and tubes which run across the individual's face. Again using a reasonable broad interpretation of the claim, the examiner has concluded that the straps and tubes disclosed by Landis and Wilkie do not extend substantially beyond a region which lies vertically between the top of the individual's forehead and the individual's upper lip and the region lying horizontally between a left eye and a right eye of the individual as observed in Fig. 6 of Wilkie et al. and Fig. 1 of Landis. Further the claim states that the apparatus "can" be attached to the individual's head so that the apparatus does not extend substantially beyond a region. Inherently the devices of Landis and Wilkie et al. may be placed on the head of a user without the strapping so that the apparatus does not extend substantially beyond the specified region. Further the argument stating that Wilkie et al and Landis do not attach a nose piece to an area above the upper lip and below the nose, but rather have a different attachment means is not persuasive. The examiner would like to first point out that the exact claim language used in claim 33

states "a means for attaching the second device to an area at or near the individual's upper lip," and not to an area above the upper lip and below the nose as stated within the arguments. Both the devices of Wilkie et al. and Landis et al. include a means for doing so. The prior art of Landis does disclose further limitations with regard to the configuration of the first device and the second device. Claim 34 remains rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 6, 19, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2003/0172936 to Wilkie et al.

6. With regards to claim 6, what is taught and shown by Wilkie et al. in Fig. 1, 2, and 6 is a nasal cannula apparatus comprising a body portion (18); a first hollow tube (part 26 on left) protruding out of the body portion; and a second hollow tube (part 26 on

right) protruding out from the body portion; a first device (12, 14, and 18) for attaching the first and second hollow tubes to an individual's head (attached to head via strap 110 through aperture 16); wherein a first end of the first hollow tube (part 26 on left) can be inserted into a first nostril of an individual (see figure 6); wherein a first end of the second hollow tube can be inserted into a second nostril of the individual (see figure 6); wherein the nosepiece (18) is further comprised of a flap portion (12); and wherein the nose piece is configured so that the nose piece can be attached to the individual's head so that the flap portion does not touch a nose of the individual but touches skin between the nose and an upper lip of the individual, while at the same time the first end of the first hollow tube is inserted into the first nostril and the first end of the second hollow tube is inserted into the second nostril (see figure 6); and wherein the apparatus can be attached to the individual's head so that the apparatus does not extend substantially beyond a region; wherein the region lies vertically between the top of the individual's forehead and the individual's upper lip and the region lies horizontally between a left eye and a right eye of the individual (See Fig. 6). Since the applicant never defines exactly what extending "substantially" beyond a region entails, using a reasonable broad interpretation of the claim, the examiner has concluded that the straps disclosed by Wilkie do not extend substantially beyond a region which lies vertically between the top of the individual's forehead and the individual's upper lip and the region lying horizontally between a left eye and a right eye of the individual as observed in Fig. 6.

7. **With regards to claim 19**, what is taught and shown by Wilkie et al. in figures 1, 2, and 6 is a method comprising the steps of attaching first and second hollow tubes to

an individual's head (paragraph 68); inserting a first end of the first hollow tube (part 26 on left) into a first nostril of an individual (fig. 6) and inserting a first end of the second hollow tube into a second nostril of the individual; and wherein the first and second hollow tubes protrude out from a body portion of a nose piece (18; fig. 6) and wherein the first and second hollow tubes are attached to the individual's head through the nose piece (fig. 6), which is attached at or near the upper lip of the individual; and wherein the nose piece includes a flap portion (12); and wherein the nose piece is configured so that the nose piece can be attached to the individual's head so that the flap portion does not touch a nose of the individual but touches skin between the nose and an upper lip of an individual, while at the same time the first end of the first hollow tube is inserted into the first nostril and the first end of the second hollow tube is inserted into the second nostril (see fig. 6; see paragraphs 21-25); and wherein the apparatus can be attached to the individual's head so that the apparatus does not extend substantially beyond a region; wherein the region lies vertically between the top of the individual's forehead and the individual's upper lip and the region lies horizontally between a left eye and a right eye of the individual (See Fig. 6). Since the applicant never defines exactly what extending "substantially" beyond a region entails, using a reasonable broad interpretation of the claim, the examiner has concluded that the straps disclosed by Wilkie do not extend substantially beyond a region which lies vertically between the top of the individual's forehead and the individual's upper lip and the region lying horizontally between a left eye and a right eye of the individual as observed in Fig. 6.

8. **With regards to claim 30**, what is taught and shown by Wilkie et al. is a nasal cannula apparatus in which the flap portion (12) is flexible (paragraph 21).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. **Claims 7 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication US 2003/0172936 to Wilkie et al. in view of U.S. Patent No. 5682881 to Winthrop et al.**

10. **With regards to claim 7**, what is taught and shown by Wilkie et al. are all the limitations of the disclosed invention defined by claim 6 with the exception of utilizing an adhesive strip for taping the flap portion of the nose piece to the individual. What is taught and shown by Winthrop et al. in figure 4 are adhesive strips (36, 38, and 40) for taping the flap portion of the nose piece to the individual (see figure 4; Col. 5, lines 29-42). It would have been obvious to one ordinary skill in the art at the time the invention was made to secure the flap portion of the nosepiece on the nasal cannula device taught by Wilkie et al. to utilize adhesive strips as taught by Winthrop et al. because it is well known in the art that adhesive strips are an effective means of securing a nasal cannula device to a user so that it may remain in the proper configuration to deliver gas to a user.

11. **With regards to claim 20**, what is taught and shown by Wilkie et al. is a nasal cannula apparatus embodying all the limitations of the disclosed invention defined in claim 19 and 20 with the exception of the method wherein the nose piece is attached by

an adhesive, which adheres the flap portion of the nose piece to the individual at or near an upper lip of an individual. What is taught and shown by Winthrop et al. in fig. 4 is the method wherein the nosepiece (18) is attached by an adhesive (36, 38, and 40) which adheres the flap portion of the nose piece to the individual at or near the an upper lip of the individual (see figure 4; Col. 5, lines 14-42). It would have been obvious to one ordinary skill in the art at the time the invention was made to secure the flap portion of the nosepiece on the nasal cannula device taught by Wilkie et al. to attach the nose piece to the user at or near an upper lip via adhesive strips as taught by Winthrop et al. because it is well known in the art that adhesive strips are an effective means of securing a nasal cannula device to a user so that it may remain in the proper configuration to deliver gas to a user. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of delivering gas to a user as taught by Wilkie et al. to adhere the flap portion (12) of the nose piece to the user at or near the upper lip because the upper lip provides a flat surface located very close to the nose that would provide a suitable surface for an adhesive to be applied so that the tubes can be secured within the nostrils of the user.

12. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0172936 to Wilkie et al. in view of U.S. Patent Application Publication US 2005/0028823 to Wood.

13. With regards to claim 31, what is taught and shown by Wilkie et al. is a nasal cannula apparatus that discloses the applicant's invention with the exception of having a flap portion comprised of a pliable synthetic polymer. What is taught by Wood in Figure

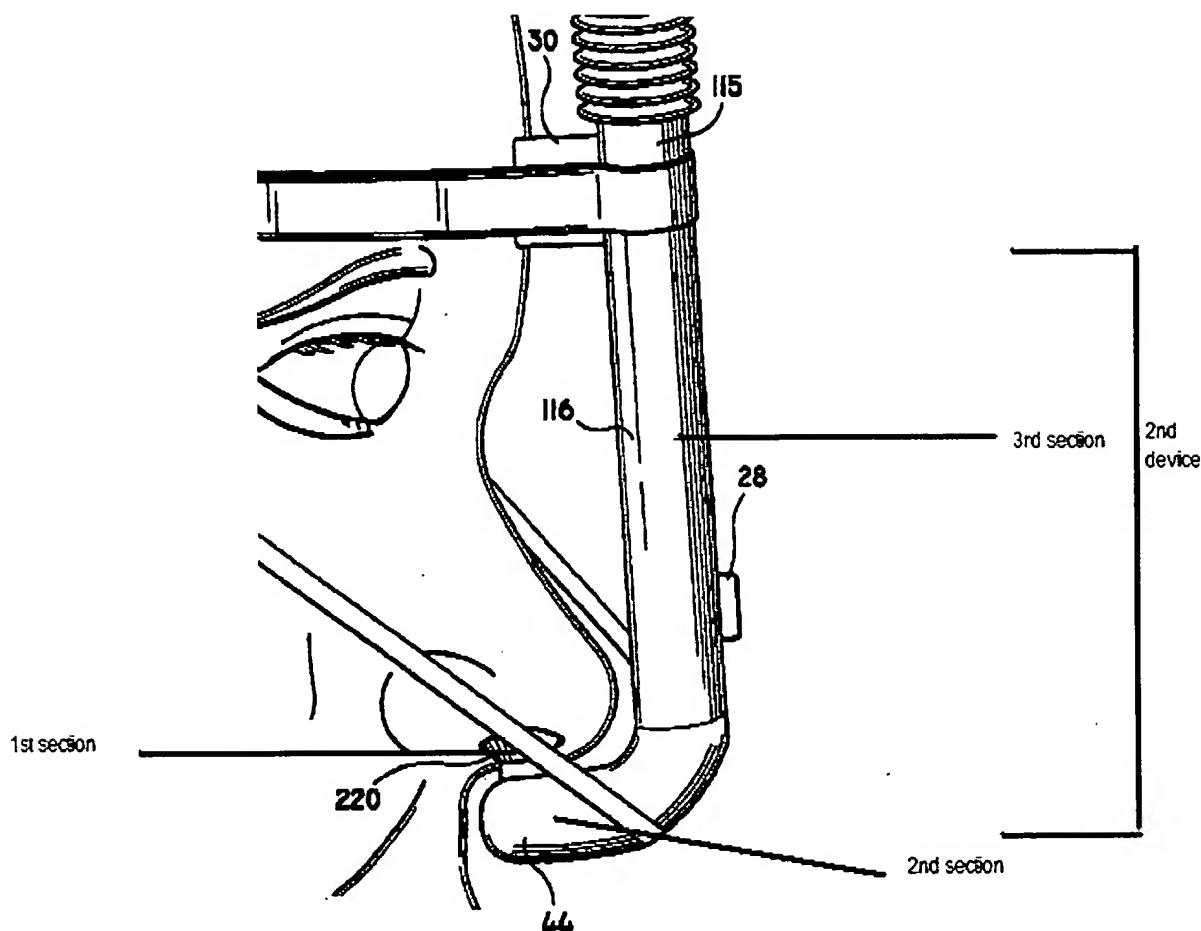
1 is a nasal cannula apparatus in which he states that body 32 can be made up of "a polycarbonate, plastic, polymer, metal, ceramic, composite, or other material known in the art (paragraph 47)." It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the flap portion (12) of the nasal cannula apparatus taught by Wilkie et al. to utilize a pliable synthetic polymer as taught by Wood to make the flap portion because it is well known in the art that polymers are durable materials and can withstand everyday wear and tear.

14. **With regards to claim 32**, what is taught and shown by Wilkie et al. is a nasal cannula apparatus that discloses the applicant's invention with the exception of having a flap portion comprised of polyvinyl chloride and silicone rubber. What is taught by Wood in Figure 1 is a nasal cannula apparatus in which he states that body 32 can be made up of "a polycarbonate, plastic, polymer, metal, ceramic, composite, or other material known in the art (paragraph 47)." After reviewing the specification, the examiner concludes that at no point does the applicant establish any criticality for utilizing polyvinyl chloride (pvc) and silicone rubber to make the flap portion. Therefore it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to use pvc, silicone rubber, or any other combination of materials used that are well known in the art to compose the flap portion that would be effective in supporting the device on the face of the user and withstand daily wear and tear for a long time.

15. **Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. U.S. Patent No 5687715 to Landis et al. in view of U.S. Patent application publication US 2004/00445553 to Cardoso.**

16. **With regards to claim 33**, what is taught and shown by Landis et al. in the figure 1 and the figure 3 shown below (devices shown in Fig. 1 and 3 are equivalent embodiments of the invention; although the embodiment shown in Fig. 1 is not shown in the side view as its alternative in Fig. 3, it is inherent that it would have the same configuration from the side view with the only difference being it utilizes two separate tubes 16,20 & 18,22 as opposed to the one large tube 116 utilized in the alternative embodiment shown in Figs. 2 and 3) is an apparatus for use in supplying air to an individual comprising a first device (10 and 30 Fig. 1; 115 and 30 Fig. below); a second device (Fig. 1: 16, 20 & 18,22; Fig. 3 shown below: 116, 44, and 220); a means for attaching the device to an individual's forehead (24); a means for attaching the second device to an area at or near the individual's upper lip (38 and 40; actually attach to a strap to hold apparatus in nares of nose as stated in Col. 6, lines 55-59; being attached into the nose is inherently near the upper lip); first and second hollow tubes (20 and 22) connected to the second device, wherein the first and second hollow tubes have first and second ends, respectively, which can be inserted into first and second nostrils, respectively, of an individual (see. Fig. 1); wherein the first device is connected to the second device (connected via connectors 32 and 34) so that air can flow from the first device to the second device and to the first and second hollow tubes (see fig. 1); wherein it has a means for attaching the second device (hooks 38 and 40 on 20 and 22

attach to strap 26 that is fixed to head band 24; Col. 6, lines 55-59); wherein the apparatus can be attached so that the apparatus does not extend substantially beyond a region: wherein the region lies vertically between the top of the individual's forehead and the individual's upper lip and the region lies horizontally between a left eye and a right eye of the individual; and wherein the first device (10) can be attached substantially parallel to the face of the individual, within the region, and to the forehead of the individual, while at the same time a first section (labeled in Figure 3 shown below) of the second device is attached substantially parallel to the face to an area at or near the individual's upper lip, and within the region, while at the same time, a second section (labeled in figure 3 shown below) of the second device is substantially perpendicular to the face and within the region, and a third section (labeled in figure 3 shown below) of the second device is substantially parallel to the forehead and within the region. What is not taught is that the means for attaching the first device does not circle the head of the individual to attach the first device. What Cardoso teaches in figure 5b is attaching the nasal apparatus nosepiece to the user by using a forehead crossbrace 35 on the forehead of the user that does not circle the head of the user. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the nasal cannula apparatus disclosed by Landis et al. to include a forehead cross brace that does not circle the head of the user as taught by Cardoso so that the user may comfortably wear the apparatus while lying down without having the discomfort of a strap pressing against the back of the head of the user as they lay down and sleep.



17. With regards to claim 34, what is taught and shown by Landis et al. in figure 1 is an apparatus wherein the means for attaching the first device (10) is located substantially at the individual's forehead; and the means for attaching the second device is located substantially at or near the individual's upper lip (38 and 40; actually attach to a strap to hold apparatus in nares of nose as stated in Col. 6, lines 55-59; being attached into the nose is inherently near the upper lip), and within the region (See Fig. 1); and wherein the first, second, and third sections of the second device are flexible

(Col. 6, lines 45-49 states that tubes 16 and 18 are flexible, Fig. 5, Col. 33-40 Landis discloses an embodiment of the nasal insertion members being flexible;)).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

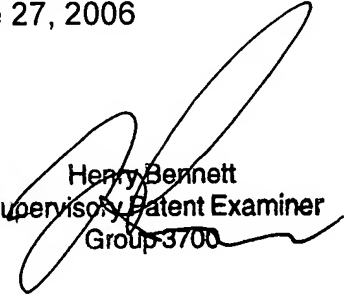
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Amadeus S Lopez
Examiner
Art Unit 3743
June 27, 2006

ASL


Henry Bennett
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